DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
M3852N

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

June 9, 2000

WARNING LETTER
CHI-22-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Donald Orr, President
United Feeds, Inc.
P.O. Box 108
Sheridan, IN 46069

Dear Mr. Orr:

An inspection of your medicated feed facility located at #1 United Lane, Griggsville, Illinois, was made by the Illinois Department of Agriculture, under federal contract, on February 8, 9, 10 and 14, 2000. This inspection found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds [Title 21, Code of Federal Regulations (21 CFR), Part 225]. Such deviations cause medicated feeds being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for, manufacturing, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices. The significant deviations noted are as follows:

- Failure to have adequate space for the storage and weighing of drug components used in feed production.

- Failure to have records indicating that scales and meters used in feed manufacture had been checked to verify they had been correctly functioning.

- Failure to maintain lot identity of type A medicated articles placed in bulk containers in the drug storage area.

- Failure to prevent excess accumulation of dust and feed components in drug weigh-up area. Covers to bulk drug containers stored in this area did not fit the containers tightly, protecting drug contents of the containers.

- Failure to have required potency assay reports on file for feeds containing Carbadox for the calendar year of 1999.

- Failure to sample finished feed in such a manner that the sample is representative of finished feed in that 5 of 19 assay samples were collected as meal while finished product form was a pelleted feed.

- Failure to perform required follow-up investigations to reported out of limits Assays for feeds containing Roxarsone, reported on 10-11-99 and 12-22-99.

- Failure to maintain label storage in a manner to prevent label mix-up.

- Failure to have written procedures for cleaning of delivery trucks to prevent commingling and cross contamination.

The violations listed above are not intended to be all-inclusive. It is your responsibility as a medicated feed manufacturer to assure that all of your operations are in compliance with the law. At the conclusion of the inspection, Form FDA 483, Inspectional Observations, was issued to and discussed with Gerold S. Parkins, General Manager Feed Division. This form is a comprehensive list of deviations observed by the Inspector during this inspection. A copy of this form is enclosed for your information.

You should take prompt action to correct these violations and establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions without further notice.

You should respond to this office in writing within 15 days from receipt of this letter, to inform us of the steps you have taken to correct the noted violations and prevent their recurrence. Please direct your response to Paul A. Boehmer, Compliance Officer, at the FDA Chicago District Office.

Sincerely,

\s\
Raymond V. Mlecko
District Director

Attachment: FDA-483

cc: Gerold S. Parkins
General Manager, Feed Division
#1 United Lane, P.O. Box 131
Griggsville, IL 62340